

CUAs has accelerated in recent years. Use of recommended methods has increased, although a sizeable number of analyses still do not adhere to best practice. Continued monitoring of these trends is crucial to enhancing the quality of the field.

MC2

15DS—A NEW DYNAMIC QUALITY OF LIFE TOOL WITH INCREASED SENSITIVITY AND IMPROVED COMPOSITE STRUCTURE FOR RECALL BIAS AND RESPONSE SIFT ADJUSTMENTS

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OBJECTIVES: Response sift (RS) and recall bias (RB) cause problems in patient-reported outcomes (PRO). RS refers to the change of meaning in health-related quality of life (HRQoL) in pretest-posttest design. RB is the result of variation in the recall of earlier HRQoL states, satisfaction and symptoms. To present a new composite HRQoL tool for integrating contemporaneous items with recall/response items. The innovative aim of the generic 15Ds tool is the adjustment of RB/RS. **METHODS:** The widely utilized 15D tool yields both 15-dimensional health profiles and an overall HRQoL index. The 15D was promoted by the WHO health definition and the additive valuation of multi-attribute utility theory (MAU) to produce quality-adjusted life years (QALY). The 15Ds was innovated by the literature and pragmatic experience with the 15D. **RESULTS:** The 15Ds contains 15 contemporary dimensions with five states (i.e. the conventional 15D), 15 recall/response dimensions with six states for transitions, and three validation dimensions. The recall/response dimensions adjust subjects' contemporary states for RB/RS. The validation dimensions contain a comparison of the subject's general health state to the health of a same-age population (5 states), RB/RS comparison for health transitions (6 states), and comparison for the level of healing (illness conceptualization, 5 states). A preliminary analysis revealed that patients have more sensitivity for changes measured as the recall/response items than for changes in the contemporary items over time. The 15Ds gives slightly better outcomes in the index changes and offers higher discrimination for the changes of HRQoL when compared with the conventional 15D. **CONCLUSIONS:** The 15Ds can produce 15-dimensional contemporary health profiles, 15-dimensional recall/response health profiles, overall HRQoL index for both 15Ds and 15D, and approximations for the validation of transitions, health and illness. The 15Ds is recommended for recall (e.g. acute conditions when no baseline HRQoL is obtainable) and RB/RS adjustment.

MC3

USING SIMULATIONS TO EXPLORE THE INFLUENCE OF COMPETING RISK ON TREATMENT-EFFECT

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OBJECTIVES: In previous work, we explored through computer-aided simulated clinical trials how heterogeneity of baseline risk can lead to heterogeneity of treatment-effect under a variety of assumptions. We now explore how heterogeneity of competing risks affect treatment-effect heterogeneity under a variety of assumptions. **METHODS:** Using simulated clinical trials in which the intervention has a constant effect on disease-specific risk (odds ratio = 0.7) but no effect on competing risk

and in which outcomes in individuals are determined by varying 2 parameters: (1) the overall risk of the outcome of interest and (2) the ratio between the competing risk and the disease-specific (i.e. treatment-responsive) risk. **RESULTS:** Under conditions in the simulations, the odds ratio of the treatment-effect on the overall outcome is highly dependent on the ratio of the competing and disease-specific risk, decreasing as this ratio increases. Although the absolute treatment-effect increases with increasing overall risk, the odds ratio for the treatment decreases as the overall risk increases (holding constant the ratio between disease-specific and competing risk). When disease-specific outcomes are measured, a similar relationship between treatment-effect and overall risk is observed, although the decrease in the odds ratio with increasing risk is greatly attenuated. Detecting significant treatment-effect heterogeneity (on the odds ratio scale) based on competing risk is likely to occur only when competing risk is very high or when patients can be sub-grouped by variables which distinguish between disease-specific and competing risk. **CONCLUSION:** The ratio of competing risk to disease-specific risk in a population can have an important impact on the measured treatment effect, even when disease-specific outcomes are measured. Detection of competing-risk-based treatment-effect heterogeneity may depend on the identification of risk factors that differentiate disease-specific from competing risk. Simulations can be useful to anticipate the magnitude of these effects when planning a clinical trial.

MC4

BREAKING THE SILENCE: THE EFFECTS OF EXPLICIT INSTRUCTIONS ON INCORPORATING INCOME IN TTO EXERCISES

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OBJECTIVES: The recommendation of the US Panel to incorporate productivity costs in terms of health effects (QALYs) in a cost-effectiveness analysis aroused quite some debate. A crucial yet under-explored question in this debate is whether people include effects of ill-health on income in health state valuations (HSV). The same holds for the actual inclusion in HSV of the effects of ill-health on leisure. This study aims to test whether respondents to health-state valuations using TTO questions include the effects of ill-health on income and leisure when the measure is silent on both. Moreover, it tests the consequences of explicit instructions to either include or exclude the income-effects in HSV. **METHODS:** Three questionnaires were developed and administered among the general public. Respondents were asked to value three distinct EQ-5D health-states using TTO. In version 1 respondents did not receive instructions on including or excluding income-effects in their valuations, but inclusion was assessed afterwards. In versions 2 and 3 respondents were instructed upfront to incorporate income-effects or to assume that income would not change. They were furthermore asked whether they included the effects of ill-health on leisure-time in their HSV. **RESULTS:** In version 1 64% of the respondents spontaneously included income-effects in their HSV. In version 2 and 3 88% included leisure-time. There were no differences in the valuations of respondents including or excluding income-effects, also in case of explicit instruction. Inclusion of leisure-time resulted in a significantly lower TTO-value in only one of the three health-states. **CONCLUSIONS:** Respondents do not consistently include income- and leisure-effects in their valuations. Including income-effects (spontaneously or instructed) does not seem to affect TTO-valuations and may therefore best be placed on the cost-side of the cost-effectiveness ratio. Leisure-

time may be more influential, but more research is needed to ensure appropriate consideration and valuation of leisure.

PATIENT REPORTED OUTCOMES

PRI

HEALTH RELATED QUALITY OF LIFE IN DIFFERENT STATES OF BREAST CANCER

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OBJECTIVES: The aim of this study was to describe the health related quality of life (HRQoL) in different breast cancer disease states using preference-based measures. **METHODS:** A total of 361 consecutive breast cancer patients attending the breast cancer outpatient clinic at Karolinska University hospital Solna for outpatient visits between April and May 2005 were included in the study. The EQ-5D self classifier and a direct Time Trade Off (TTO) question was used to estimate the HRQoL in different breast cancer disease states. **RESULTS:** All of the different disease states had lower HRQoL compared to the general population. Patients in their first year after a primary breast cancer had a mean EQ-5D index value of 0.696 (95% confidence interval (CI): 0.634–0.747). Patients in their first year after a recurrence had a mean EQ-5D index value of 0.779 (CI: 0.700–0.849). Patients whom had not had a primary breast cancer diagnosis or a recurrence during the previous year had a mean EQ-5D index value of 0.779 (CI: 0.745–0.811). Patients with metastatic disease reported the lowest HRQoL values, and had a mean EQ-5D index value of 0.685 (CI: 0.620–0.735). The main driver behind the reduction in HRQoL was pain and discomfort as well as anxiety and depression. TTO values were higher for all diseases states compared to the EQ-5D index values. **CONCLUSION:** This study shows that breast cancer is associated with a reduction in HRQoL. This effect is most pronounced for patients with metastatic disease. Our results also indicate that breast cancer has a permanent negative effect on HRQoL, even if the patient remains recurrence free.

PR2

ESTIMATING UTILITY VALUES FOR HEALTH STATUS USING THE SPANISH VERSION OF THE SF-36. DATA OF VALIDITY OF THE SF-6D VS EQ-5D IN SPAIN

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OBJECTIVES: A new utility index derived of the SF-36, the SF-6D, was recently developed and has generated an increasing research in different groups of patients and has also been compared with other utility measures, as it is the EQ-5D. The purpose of the present work is to validate this index in the Spanish version of SF-36 with respect to the Spanish version of the EQ-5D. **METHODS:** A total of 1843 complete measures of the SF-36 (version 2) and the EQ-5D (5 items and visual analogic scale-VAS) from 1283 patients who received a solid organ transplant (kidney, liver, heart or lung) were used. Data were collected at different moments during the first year after the surgery in the context of the Spanish Research Network on Transplantation. SF-6D values were calculated using the model proposed by its creator. EQ-5D values were calculated using Spanish VAS tariff (VAS-t) and time-trade off tariff (TTO-t). Spearman correlation coefficients were calculated between SF-6D and EQ-5D values. **RESULTS:** Mean value (SD) of SF-6D was 0.67 (0.15) (range 0.3–1.0), of EQ-5D VAS-t, 0.69 (0.24) (range –0.08–1.0) and of TTO-t, 0.70 (0.32) (range –0.7–1). Percentage of subjects

scoring the maximum was 1.1% for SF-6D, and 24.5% for the EQ-5D. SF-6D values had moderate correlation with EQ-5D VAS-t ($r = 0.734$) and EQ-5D TTO-t ($r = 0.731$) (both $p < 0.001$). **CONCLUSIONS:** The SF-6D index derived from the Spanish version of SF-36 seem to be a valid utility index to be used with the SF-36 databases from studies made in Spain. However the moderate correlation between both utility measures indicates that probably they partially measure different concepts.

PR3

LOW ADHERENCE WITH GASTROPROTECTIVE AGENTS WHEN CO-PRESCRIBED WITH NSNSAIDS ASSOCIATED WITH INCREASING RISK OF GI-RELATED HOSPITALISATION

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OBJECTIVE: Lack of adherence with gastroprotective agents (GPAs) when prescribed with non-selective (ns) NSAIDs may increase risk of hospitalisation for gastrointestinal (GI) conditions. This study assessed the effect of frequent nsNSAID use with varying levels of GPA use on GI outcomes. **METHODS:** Prescription data from a primary care database (DIN-LINK), representative of the UK population, containing records of over 800,000 patients, was used. Patients with osteoarthritis and/or rheumatoid arthritis who received nsNSAID therapy and co-prescribed GPA between September 2003 and August 2005 were identified. Adherence (proportion of days covered (%)) at monthly intervals was defined as days on gastroprotective therapy within a moving window of three consecutive months on nsNSAID. Patients were assessed according to their level of GPA use (0–19, 20–39, 40–59, 60–79, 80–99, 100%). Records of hospitalisation for GI conditions (also available in the database) at monthly intervals were analysed as a function of GPA adherence. Odds ratios of GI-related hospitalisation between cohorts of varying GPA use were calculated. Additional analysis was performed according to GI risk factors. **RESULTS:** The database identified 15,956 patients with an NSAID prescription for at least 75% of the examined period, and of these, 8890 patients with a GPA co-prescription with at least 20% use. The rate of GI-related hospitalisation for the defined period was 2.49% with full (100%) GPA use. The odds ratio for GI related hospitalisation of the sub-cohorts vs. that with 100% adherence (95% CI), in decreasing order according to adherence, was 1.57 (1.14–2.16), 1.49 (0.95–2.36), 2.85 (1.84–4.43), 3.52 (2.28–5.44), 1.47 (1.19–1.81). The odds of GI-related hospitalisation were up to 3.5 times higher for NSAID users with poorer GPA adherence. **CONCLUSION:** Analysis of observational clinical and prescription data revealed that the lower the GPA use of frequent NSAID users, the higher the rates of hospitalisation for GI conditions.

PR4

PREFERENCES OF PEOPLE WITH DIABETES FOR INHALED AND INJECTABLE INSULIN REGIMENS

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OBJECTIVE: To elicit single-index preferences from people with diabetes for treatment with inhaled insulin compared to injectable insulin. **METHODS:** Written descriptions were developed for five clinical scenarios in Type 1 and Type 2 diabetes (T1D and T2D): 1) pre-mixed insulin in T1D; 2) basal-bolus insulin in T1D; 3) pre-mixed insulin in T2D; 4) oral treatment in T2D; and 5) oral treatment plus basal insulin in T2D. In each scenario, adjustment or initiation of insulin treatment was